

REMARKS

Status of the Claims

Claims 1-26 were originally pending. Claims 1-16, 24-25 have been cancelled. Claims 17-23 and 26 are pending. Claims 17-23 and 26 have been rejected. Reconsideration of the application is respectfully requested.

The Rejection Under 35 U.S.C. §102(e) Should be Withdrawn

Claims 17-23 and 26 were rejected under 35 U.S.C. 102(e) as being anticipated by Hung *et al.* (USP No. 6,413,228). The Examiner argues that Hung *et al.* discloses a system of cytological evaluation of epithelial cells (Abstract & Column 28 line 51- Column 29 line 14) collected from a human breast duct comprising:

- A tool (Figure 3) for accessing a breast duct and collecting breast duct fluid from a human breast while the tool is in the duct;
- A chart or written guidelines (Column 13, lines 66-Column 14 line 12) for evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin

distribution, coarseness of chromatin, and the presence or absence of microcalcifications (Column 13, lines 51-55 & Column 25, lines 6-33); and

- An algorithm (Column 12, line 56- Column 17, line 10 & Column 26, lines 35-48) for classifying the sample as being normal, atypical or malignant based upon the observed indicia.

The Applicants respectfully traverses this rejection.

It is the Applicants' position that Hung *et al.* does not anticipate the present claims. "[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every limitation of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Systems, Inc. v. Kent State University, 212 F.3d 1272 (Fed. Cir. 2000). Hung *et al.* does not meet this standard.

The claimed invention teaches a system of cytological evaluation of epithelial cells collected from a human breast duct comprising: a tool for accessing a breast duct and collecting breast duct fluid from a human breast while the tool is in the duct; a chart or written guidelines for evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications; and an

algorithm for classifying the sample as being normal, atypical or malignant based on the observed indicia.

The Examiner has not pointed out with clarity and specificity where every limitation of the claimed invention, either expressly or inherently, can be found within the four corners of Hung *et al*. According to the Federal Circuit, anticipation requires the disclosure of "...a single prior art reference of each element of the claim under construction." (W.L. Gore & Assocs. vs. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983)). It is not enough that the reference disclose all of the elements in isolation. The Federal Circuit has stated that a prior art reference must disclose each of the elements of a claimed invention "arranged as in the claim". (see Lindemann Maschinenfabrik GmbH vs. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 193 (Fed. Cir. 1984). The prior art reference Hung *et al*. does not disclose each of the elements of the claimed invention arranged as in the present claims.

The claims of the present invention disclose a system of cytological evaluation of epithelial cells collected from a human breast duct comprising:

- A tool for accessing a breast duct and collecting breast duct fluid from a human breast while the tool is in the duct;
- A chart or written guidelines for evaluating the ductal epithelial cells in the sample; and
- An algorithm for classifying the sample as being normal, atypical or malignant based upon the observed indicia.

The claimed invention is a system containing a tool for accessing a breast duct; a chart or written guidelines; and an algorithm; together to assist in the cytological evaluation of epithelial

cells collected from a human breast duct. The Examiner points to different sections of the specification of Hung *et al.* as support for the argument that Hung *et al.* teaches the system of the present invention. However, the Examiner makes no mention in the Office Action of the reasoning why those particular sections anticipate the claims of the present invention. For instance, the Examiner rejects claims 17 and 26 under 102(e) because the limitation of “a chart or written guidelines for evaluating the ductal epithelial cells in the sample” is apparently anticipated by Column 13, lines 66-Column 14 line 12 of Hung *et al.* Column 13, line 66-Column 14 line 12 of Hung *et al.* merely list several published methods for studying atypical growth patterns of cells. There is simply no mention of charts or written guidelines for evaluating the ductal epithelial cells in a sample.

Likewise the Examiner rejects claims 17 and 26 under 102(e) because limitation of “an algorithm for classifying the sample as being normal, atypical or malignant based upon the observed indicia” is apparently anticipated by Column 12, line 56- Column 17, line 10 & Column 26, lines 35-48 of Hung *et al.* Column 12, line 56- Column 17, line 10 & Column 26, lines 35-48 of Hung *et al.* is a very large section of the specification listing examples of cellular material, exemplary markers, animal models, and cytological assays. There is simply no mention of an algorithm for classifying a sample as being normal, atypical or malignant based upon observed indicia. In fact, the word “algorithm” does not appear anywhere in the specification of Hung *et al.*

Thus, the Applicants are perplexed as to how the Examiner can make a rejection of the present claims under 102(e) without any explanation as to why the particular sections of Hung *et*

al. anticipate the claims of the present invention especially since specific elements of the claims are not mentioned anywhere in the prior art.

Accordingly, for the reasons stated above, Claims 17, 26 and all claims depending therefrom are allowable. Withdrawal of the rejection is requested.

Conclusion

In light of the arguments presented above, the Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited. It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.017011.

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